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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,987	09/11/2000	John P. Vanden Heuvel	7024465PUR99	9345

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/555,987	VANDEN HEUVEL ET AL.
	Examiner San-ming Hui	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 September 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Applicant's amendment to claims 1, 4, 6, 9, 13, and 14 filed August 14, 2001 is acknowledged.

The outstanding rejection of claims 9 and 10 is removed in view of the amendment of the claims filed September 24, 2001.

The outstanding rejection of claims 1-15 under 35 USC 112, first paragraph is removed in view of applicant's remarks filed September 24, 2001 regarding the specification disclosing enough working examples to enable the claimed invention and the claims actually being limited to a limited number of conjugated linoleic acid (CLA), $C_{18}H_{32}O_2$.

Claims 1-21 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Boer et al. (US Patent 5,518,751) in view of Satter et al. (US Patent 5,770,247 from the Information Disclosure Statement received March 30, 2001), references of record in the previous office action mailed June 20, 2001.

de Boer et al. teaches that CLA in food compositions such as milk products are useful in treating disorders such as diabetes (See particularly col. 1, line 35 to 43).

de Boer et al. does not expressly teach particularly CLA is useful in a method of treating diabetes. de Boer et al. does not expressly teach that the conjugated linoleic acid is *trans,cis*-9,11-octadecadienoic acid, *cis,cis*-9,11-octadecadienoic acid, or *trans,cis*-10,12-octadecadienoic acid. de Boer et al. does not expressly teach that the amount of the conjugated linoleic acid is about 1mg to about 10,000mg/kg of body weight in the invention.

Satter et al. teaches a method of adding linoleic acid compounds into animal feed and cow's milk (see particularly claim 1). Satter et al. also teaches the linoleic acid compounds to be used may include *trans,cis*-9,11-octadecadienoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid (See particularly col. 5, line 51 to col.6 line 50).

It would have been obvious to one skill in the art when the invention was made to employ CLA in a method of treating diabetes. It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans,cis*-9,11-octadecadienoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid into a milk composition product useful in a method of treating diabetes.

One of ordinary skill in the art would have motivated to employ CLA in a method of treating diabetes because de Boer et al. clearly suggest fatty acids including CLA is useful to treat disorders including diabetes.

One of ordinary skill in the art would have been motivated to incorporate the CLA compounds herein in the amounts herein into milk food composition products useful in a method of treating diabetes because CLAs, broadly, are known to be useful in a method and composition for treating diabetes. Therapeutic effects in the treatment of diabetes would have been reasonably expected when using any particular known CLA compounds including the compounds herein in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan, absent evidence to the contrary.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, example 4, the only example containing comparative data on the antidiabetic effectiveness of CLA, has been considered but not found persuasive because the effect of CLA on diabetes is expected based on prior art: CLA improves the plasma insulin level and glucose

tolerance (See Figure 10 and Table 3). No clear or convincing unexpected results is seen to be present herein.

Response to Remarks

Applicant's remarks filed September 24, 2001 regarding the teaching of de Boer et al. being too broad and therefore not suggesting linoleic acid being useful in treating diabetes has been considered but not found persuasive because de Boer et al. clearly teaches that unsaturated fatty acid including conjugated linoleic acids (CLA), are useful in the treatment of diabetes (See col. 1, lines 35-42; particularly line 39 and 40).

Applicant's remarks that this passage in the de Boer patent encompasses many fatty acid compounds are not persuasive since clear motivation for the claimed method employing a conjugated linoleic acid in the treatment of diabetes and a reasonable expectation of success for the invention is provided by de Boer. Note also in this regard that claim 1 for instance, encompasses the employment of a large number of compounds, i.e., any conjugated linoleic acid type compounds. If it is applicants position that the US Patent to de Boer is not enabled insofar as it relates to the claimed invention herein, applicants are requested to note that US Patents are presumed valid and enabled.

Applicant's assertion filed September 24, 2001 that one cannot determine what compounds are useful in treating the listed disorders in de Boer et al. has been considered but not found persuasive because de Boer et al. clearly states that CLA is

one of the preferred compounds for treating disorders such as diabetes (See col. 1, line 39-40).

Applicant's remarks regarding de Boer et al. and Satter et al. individually not teaching the instant invention have been considered but are not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Even though Satter et al does not teach CLA is useful for treating diabetes, the combination teaching between de Boer et al. and Satter et al. clearly motivates one of ordinary skill in the art to put CLA into a milk product since CLA, as discussed above, is known to be useful in treating diabetes based on de Boer et al.

In response to Applicant's questions regarding Satter et al.'s teaching of putting vegetable oil rich in CLA into cow's feed, Satter et al. actually teaches the reason for putting vegetable oil rich in CLA into cow's feed is that an unexpected increase in the CLA content in lactating cows' milk could be achieved (See col. 1, line 61-67; and col. 2, line 34-43). Please note that this reference has been employing in the instant combination rejection especially for its teaching that preferred linoleic acids such as *trans,cis*-9,11-octadecenoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid are known to be added into animal feed and milk.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the prior art, e.g., de Boer et al., taken with Satter et al. is seen to clearly suggest that claimed method and composition employing CLAs are useful in treating diabetes (See col. 1, line 39-40).

Applicants are further requested to note regarding the composition claimed herein, that de Boer clearly teaches the usefulness of CLA broadly, in milk composition products. In addition, Satter et al. clearly teaches employment of the preferred CLA herein in vegetable oil compositions useful in animal food product.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
December 2, 2001

Minna Moezie
MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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